

REMARKS

In response to the Office Action mailed December 10, 2008, favorable reconsideration is requested in light of the above amendments and the following remarks. Claims 17, 21-28 and 32-33 have been amended for purposes of clarity and to advance prosecution of the subject matter of commercial relevance to Applicants. Claims 18-20 and 29-31 and 34-53 have been canceled. Support for these amendments may be found throughout the specification and/or claims as originally filed. Further, these amendments are not to be confused with acquiescence to the Examiner's stated grounds for rejection and are made without prejudice to prosecution of any subject matter removed and/or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 17, 21-28 and 32-33 remain pending in the application.

Rejections Under 35 U.S.C. §101

In reply to the Examiner's rejection under 35 U.S.C. §101, on the basis that claims 17-33 and 39-51 are not presented in the format of proper process claims, the subject claims have been amended accordingly. Reconsideration of this rejection is hereby requested.

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 17-33 and 39-51 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. More specifically, according to the Examiner: (a) claims 17-33 are vague and indefinite for failing to set forth any active, positive steps that define the claimed method; (b) the recitation of "administration" in claim 33 lacks antecedent basis in claims 17 and 18; and (c) claims 39 and 40 are vague and indefinite on the basis that it is unclear what is being set forth within SEQ ID NOs: 4 and 56.

In an effort to advance prosecution, but without prejudice or acquiescence, claims 18-20, 29-31 and 39-51 have been canceled. Withdrawal of the rejection against these claims is therefore respectfully requested.

With respect to the remaining claims, this rejection is traversed and reconsideration is requested in light of the following. As for item (a), the relevant claims as

amended are now submitted to be in proper process format. The claims further recite the active step of administering to a subject a claimed isolated monoclonal antibody.

With respect to item (b), in light of the amendment to claim 17, from which claim 33 depends, proper antecedent basis is submitted to be in place.

Regarding item (c), SEQ ID NOs: 4 and 56 represent specific polypeptide sequences disclosed with particularity in the specification as originally filed. In this respect, Applicants are confused by the Examiner's assertion that it is not clear what is being set forth in these SEQ ID NOs when these polypeptide sequences are clearly and specifically disclosed in the application. Thus, to the extent this rejection is maintained, the Examiner is requested to further clarify its basis.

Rejections Under 35 U.S.C. §112, First Paragraph

Claim 41 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, according to the Examiner, Applicants were allegedly not in possession of nucleic acids encoding monoclonal antibodies that binds SEQ ID NO: 4 or 56 at the time of filing.

As noted above, in an effort to advance prosecution, but without prejudice or acquiescence, claim 41 has been canceled. This rejection is therefore now moot.

Rejections Under 35 U.S.C. §102

Claims 17, 19, 21-34, 36-39, 42-51 and 52 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kindsvogel (WO 02/066516). According to the Examiner, Kindsvogel discloses a monoclonal antibody that binds to BCMA, as well as bi-specific antibodies that bind to BCMA, where the sequence of BCMA is identical to presently claimed SEQ ID NO: 4. The Examiner also asserts that the bi-specific antibody is useful in the treatment of B lymphoma and chronic lymphocytic leukemia. The Examiner further alleges that Kindsvogel discloses a detection method wherein a biopsy sample is contacted with antibodies in order to detect the relative abundance of BCMA.

In an effort to advance prosecution, but without prejudice or acquiescence, claims 19, 29-31, 34, 36-39 and 42-52 have been canceled. Withdrawal of the rejection against these claims is therefore respectfully requested.

As for the remaining claims, this rejection is traversed.

Independent claim 17 is directed to a method for treating chronic lymphocytic leukemia (CLL) in a mammalian subject by administering to the subject an effective amount of an isolated monoclonal antibody that specifically binds to a polypeptide comprising the sequence set forth in SEQ ID NO: 4.

As described in Applicants' specification as originally filed, an antibody is said to "specifically bind" to a peptide or protein if it reacts at a detectable level but does not react detectably with unrelated peptides or proteins under similar conditions (e.g., page 26, paragraph [189] of WO 03/062401).

Applicants acknowledge that Kindsvogel describes the use of dual reactive or bi-specific antibodies in the treatment of certain hematological malignancies, including chronic lymphocytic leukemia, as noted by the Examiner. However, such antibodies are clearly required to bind both BCMA and TACI. Kindsvogel simply does not teach or suggest any monoclonal antibody that is not dual reactive or bi-specific that could or should be used in a method for treating chronic lymphocytic leukemia, as presently claimed by Applicants.

Accordingly, as present claim 17 clearly does not employ or encompass antibodies that react with proteins unrelated to BCMA, such as the antibodies described by Kindsvogel, which bind both BCMA and TACI, Applicants submit that Kindsvogel does not anticipate the present claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 31 and 41 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kindsvogel (WO 02/066516).

Claims 40 and 53 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bräuner-Osborne *et al.* (*Biochimica et Biophysica Acta*, 2001, Vol. 1518, pp. 237-248) in view of Campbell (*Monoclonal Antibody Technology*, 1984, pp. 1-32).

Claims 39 and 52 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Laäbi *et al.* (*EMBO*, 1992, Vol. 11, pp. 3897-3904) in view of Campbell (*Monoclonal Antibody Technology*, 1984, pp. 1-32).

Claims 34, 35, 38-40, 52 and 53 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Claudio *et al.* (*Blood*, Sept. 15, 2002, Vol. 100(6), pp. 2175-2186) in view of Campbell (*Monoclonal Antibody Technology*, 1984, pp. 1-32).

In an effort to advance prosecution, but without prejudice or acquiescence, claims 31, 34-35, 38-40 and 52-53 have been canceled. Accordingly, the Examiner's rejections under 35 U.S.C. §103 are now moot. Applicants further note that no rejections under 35 U.S.C. §103 have been raised by the Examiner against any of the claims presently remaining in the application.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/Jeffrey Hundley/
Jeffrey Hundley, Ph.D., Patent Agent
Registration No. 42,676

JEH:ms

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031